

REMARKS/ARGUMENTS

Status of the Claims

Claims 107 and 108 are pending after entry of the amendments presented herein.

Claims 107 and 108 have been amended. Support for the amendments can be found in the specification such as, for example, page 12, lines 9-14, page 26, lines 3-10.

The specification is amended on pages 26 to incorporate by reference the wild type sequence information cited on page 26, line 9-10. Support for the amendments is found in the specification, for example, page 24, lines 9-10, and page 46, lines 22-23. Applicants note that the amino acid sequences of wild type FucT-VI and FucT-VII were known at the time of filing of the patent application and incorporated by reference (see spec. page 24, lines 9-10) from Braunschweig Enzyme Database number EC 2.4.1.65 (see Exhibit A) and recited in Protein Database Accession No. P51993 for FucT-VI (Exhibit B), and Protein Database Accession No. Q11130 for FucT-VII (Exhibit C).

No new matter has been added.

Sequence Listing Under 37 C.F.R. §§ 1.821-1.825

The amendments are made in adherence with 37 C.F.R. § 1.821-1.825. This amendment is accompanied by a floppy disc and/or the Text (.TXT) format file containing the above named sequences, SEQUENCE ID NUMBERS 1-2, in computer readable form, and a paper copy of the sequence information in adherence with 37 C.F.R. §§ 1.825(a) and 1.825(b).

The information contained in the computer readable format is identical to that of the paper copy in adherence with 37 C.F.R. § 1.821(f).

This amendment, and the attached Sequence Listing and paper copy, contains no new matter in adherence with 37 C.F.R. § 1.825(a).

Applicants submit that this amendment, the accompanying computer readable sequence listing, and the paper copy thereof serve to place this application in a condition of adherence to the rules 37 C.F.R. §§ 1.821-1.825.

Objection to the Claims

Claim 108 is objected to because of a typographical error. Claim 108 has been amended to correct the error. Therefore, the Applicants respectfully request that this objection be withdrawn.

Rejection Under 35 U.S.C. §112, first paragraph, enablement

Claims 107 and 108 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to provide enablement for the claims. In view of the amendments to the claims and the remarks made herein, Applicants request the withdrawal of this rejection.

In maintaining the rejection, the Office Action notes that the previous arguments are not persuasive because without reference to a specific parent sequence, it would not be clear to a skilled artisan which of the infinite number of parent fucosyltransferases are encompassed in the claims (Office Action, page 7).

Solely to expedite prosecution and without conceding the propriety of the rejection, claim 107 is amended to recite “wherein said eukaryotic fucosyltransferase is a recombinantly produced FucT-VI corresponding to SEQ ID NO:1 or FucT-VII fucosyltransferase corresponding to SEQ ID NO:2”.

As such, the amendment further recites that the amino acid positions correspond to a referenced amino acid sequence (SEQ ID NO:1 or 2) as suggested in the Office Action. Applicants note that the amino acid sequence of wild type PNGase-F amidase was known at the time of filing of the patent application and incorporated by reference from the Braunschweig Enzyme Database number EC 2.4.1.65 (Exhibit A) (see specification page 26, lines 3-10).

Since the Office Action has indicated that inclusion of a specific parent sequence for the corresponding sequence would render the claims enabled, Applicant respectfully requests that this rejection be withdrawn.

Rejection Under 35 U.S.C. §112, first paragraph, written description

Claim 107 and 108 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter that was not disclosed in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention. In view of the amendments to the claims and the remarks provided herein, this rejection is respectfully traversed.

In maintaining the rejection, the Office Action asserts that the specification fails to provide adequate written description because “without reference to a specific parent sequence, it would not be clear to a skilled artisan which of the infinite number of parent FucT-VI and FucT-VII and their variants are encompassed in the claims” (Office Action, page 10).

Solely to expedite prosecution and without conceding the propriety of the rejection, claim 107 is amended to recite “wherein said eukaryotic fucosyltransferase is a recombinantly produced FucT-VI corresponding to SEQ ID NO:1 or FucT-VII fucosyltransferase corresponding to SEQ ID NO:2”.

Accordingly, the Applicants respectfully submit that the claimed methods meet the written description requirements of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection of the claims under 35 U.S.C. § 112, first paragraph is respectfully requested.

Rejection Under 35 U.S.C. §103

Claims 107 and 108 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Palcic (1989) or Ichikawa et al (1992) in view of Weston et al (1992) and Kimura et al (1999). In view of the amendments to the claims and the remarks made herein, the Applicants respectfully request that this rejection be withdrawn.

The law is clear that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992). Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 231 USPQ 375 (Fed. Cir. 1986).

Third, the prior art reference, or references when combined, must teach or suggest all the claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974).

As will be shown below, the prima facie case of obviousness here is deficient because the cited references alone, or in any combination, fail to teach each and every element found in the claims. In particular, the combination of references fails to teach use of a recombinantly produced FucT-VI or FucT-VII fucosyltransferase lacking a membrane anchoring domain.

Palcic and Ichikawa have been cited for disclosing chemical and enzymatic synthesis of glycopeptides. However, as noted in the Office Action, both Palcic and Ichikawa “are silent with respect to use of recombinant FucT-VI or FucT-VII fucosyltransferases” (Office Action, page 10). The Office Action further cites Weston and Kimura as disclosing the molecular cloning of FucT-VI and FucT-VII. However, both Weston and Kimura fail to teach FucT-VI or FucT-VII fucosyltransferases that lack membrane anchoring domains.

Accordingly, in combining the cited references, there is no teaching of a method of modifying the fucosylation pattern of a recombinant glycopeptide comprising an acceptor moiety using a recombinantly produced FucT-VI or FucT-VII fucosyltransferase lacking a membrane anchoring domain as recited in the claims.


Since the combination of cited references fails to teach each and every limitation found in the claims, the cited references cannot render the present claims obvious. As such, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Applicants respectfully request a telephone interview if the Examiner believes that the claims as amended are not in condition for allowance in light of the response submitted above. The undersigned can be reached at 415-442-1000.

Respectfully submitted,



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Enclosures:

- Exhibit A: Braunschweig Enzyme Database Reference Number EC 2.4.1.65
- Exhibit B: GenBank Accession No. P51993
- Exhibit C: GenBank Accession No. Q11130
- Paper copy of Sequence Listing
- Computer readable format of Sequence Listing in TXT format

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